

REMARKS

Applicants have previously requested continued examination, withdrawal of the previously pending Appeal, and reopening of prosecution of the application. This submission is supplemental that earlier request and submission, and clarifies what Applicants perceive to be their invention by stating that the coating on the surface of the neutral microgranules is a uniform mixture of the active principle and the optional binder. In the interest of expediting examination, and without prejudice or disclaimer, Applicants hereby cancel the claims to the tableting premix. Applicant requests entry of the foregoing amendments, reconsideration and withdrawal of all outstanding rejections, and formal notification of allowance.

Applicants Statement of the Substance of the Interview

Applicants gratefully acknowledge the in-person interview with Examiner Holt and Primary Examiner Pak (by telephone), and which further included Applicants' representative Sarah Gorintin, and Sebastien Schauinger (both by telephone). The interview substantially advanced examination.

During the interview, Applicants clarified their intention to claim a tablet having a structural distinction over the prior art in that the coated neutral microgranules making up at least 99% of the weight of the tablet have only a single-layer coating on the surface of the neutral microgranule, and do not possess any substantial or operative amounts of other coatings, layers, or other materials. That coating is a substantially uniform mixture of only the active principle and the optional binder. That is, the active principle and the optional binder are homogeneously dispersed throughout that sole, single layer. The resulting single-layer coated neutral

microgranules may then be combined with up to 1% lubricant, and are ultimately formed into the claimed tablets.

The claimed tablets are thus distinct from others, e.g., wherein a binder is first laid down on a surface of a neutral microgranule, and then an active principle and/or other ingredients are added on top of the binder. (And this is particularly so wherein the other ingredients are separate, additional layers on top of the active principle layer, e.g., polymer films, added to modify the release rate of the active principle and/or mask its taste.) Such prior art coatings represent an inhomogeneous distribution of binder, active principle, and/or other ingredients on the surface of the neutral microgranule; and would not be confused with the single-layer structure of the instant claims. Thus, Applicants distinguished such embodiments at page 7, lines 13-16 of the specification as those wherein the active principle-containing layer is further coated with another layer, e.g., a polymer film, intended to modify the release of the active principle. The embodiments claimed herein exclude such added layers.

It was agreed during the interview that the specification's description of the manner in which the binder and the active principle are combined and applied to the neutral microgranule would have been interpreted by one skilled in the art as producing a single-layer of active principle and binder in uniform (or homogeneous) admixture. See, e.g., Specification, pg. 13, lines 21-29 ("The attaching of the coating of the active principle to the neutral microgranules is carried out according to conventional methods, such as the attaching of a coating starting from solutions or suspensions, ..., optionally in the presence of binding agent in the spraying solvent."). Accordingly, Applicants now amend the claims to expressly recite that

there is a uniform mixture of active principle and optional binder as a single layer on the surface of the neutral microgranule.

Further, Applicants' use of the "consisting essentially of" transition phrase expressly restricts the compositions from including any substantial or operative additional materials or layers beyond the recited single layer of active principle and optional binder.

Claim Amendments

In accordance with the discussion during the interview with the Examiners, Applicants now amend the claims to expressly recite that the claimed tablets consist essentially of coated neutral microgranules and a lubricant, and wherein the neutral microgranules are coated with only a single layer of a uniform admixture of active principle and optional binder, and such that there are no other layers or other substantial or operative ingredients in the tablet.

Applicants have also added new claims to recite embodiments wherein the optional binder is a singular cellulosic material; and more specifically, in other dependent claims, that the binder is hydroxypropylmethylcellulose. Applicants submit that the amendments and new claims are fully supported by the specification, and so they do not add new matter.

The Cited Prior Art

As previously discussed, the cited prior art does not anticipate or suggest the claimed invention.

Bhutani describes multi-layered compositions wherein the non-pareil beads are first coated with active principle, and then with additional and varying amounts of retarding materials, and then cured in an oven. The resulting cured pellets are then coated with several layers of disintegrating agents, and compressed into tablets or pills. Bhutani, col. 4, lines 11-29. Bhutani requires numerous and distinct layers of coating and retarding materials, in addition to the active principle. As such, Bhutani does not teach the single-layer coated microgranules of the instant claims.

Harrison likewise fails to meet the limitations of the instant claims. Harrison requires that the tablets described therein be made by first coating nonpareils with a mixture of binder and active principle, and then by adding a further coating ("sustaining coating") of a mixture of at least three distinct polymer agents. *E.g.*, col. 5, lines 3-15; col 6, lines 30-64. The resulting coated particles are then combined into hard gelatin capsules. Harrison's coated nonpareils necessarily include multiple coatings, and are thus distinct from those of the instant claims. Further, Harrison compounds them into hard gelatin capsules, and so does not teach or suggest that they can be compounded as tablets, as claimed here.

Frost also describes a distinct composition. Frost requires the addition of a coating over the active principle to prevent its dissolution (e.g., methylmethacrylate); or combining the coated dosage subunits (nonpareils) with additional HPMC (in a ratio of 10:1; Example VII), which may then be compressed into tablets. Both of those embodiments are distinct from those now claimed by Applicants in that neither meets the limitation, nor does it suggest, that the resulting tablet can be fabricated from neutral microgranules coated only with active principle and optional binder in a uniform admixture; and wherein those materials are combined only with up to 1%

lubricant, and wherein there are no other substantial or operative ingredients or additives. Makino fails to teach or suggest the deficiencies of Frost. Accordingly, the claims now presented are not obvious over the combination of Frost and Makino.

Conclusion

Applicants submit that the application is in condition for allowance. Applicants request substantive examination of the claims presented herein, reconsideration and withdrawal of all outstanding rejections, and formal notification of allowance. If the Examiner perceives any impediment to such formal notification of allowance, whether formal or substantive, Applicants ask the Examiner to telephone Applicants' representative at the number provided below. Such informal communication will expedite examination and disposal of the case.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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